

Remarks

In response to the Office Action issued on October 4, 2005, Applicants have amended the abstract of the application. In addition, Applicants have amended claims 1, 3, 4, 16, 21-23, 27, 28, 32, and 34-36. Claims 6-9, 11-15, 17-20, 24-26, 29, 30, 33, and 37-39 remain pending. Claims 2, 5, 10, and 31 have been withdrawn. Claims 40-45 have been added.

The Examiner rejected Claim 1 as anticipated by Sahota, et al., U.S. Patent No. 5,417,653 (the “‘653 Patent”) and rejected Claims 3-5 as unpatentable over the ‘653 Patent. The Examiner did not include a basis for rejecting Claim 2; because Claim 3 depends on it, we assume it was rejected on the same basis as Claims 3-5.

In rejecting Claims 3-5, the Examiner notes that the ‘653 Patent does not teach the configuration of the infusion ports described in Claims 2 and 5, but contends “applicants have not disclosed that the shape, dimensions or configuration of the infusion ports provides an advantage, is used for a particular purpose, or solves a stated problem.” However, this is incorrect. To the contrary, a significant portion of the specification is devoted to discussion of the benefits of the claimed configurations. See pages 18-21 of the application. For example, the application discloses that positioning the infusion ports at intervals of about 120 degrees of substantially uniform radial separation permits equalization of the pressure of infusion fluid about the circumference of the catheter. See page 18, lines 12-14 of the application. See also the discussion at page 21, lines 1-7 of the application. In addition, the efficient elimination of blood achieved by this design is credited in part with the uniform biological response, regardless of how well the light source is centered (p. 34, lines 2-13).

As noted in the application, efficient elimination of blood is particularly critical for applications using light having a wavelength of light shorter than the wavelength of red light, because such light is highly absorbed by blood. See page 1, lines 2-5 of the application. See also the discussion at page 42, line 13 through page 43, line 5 of the application. However, the experiments disclosed in the '653 Patent involved use of red light; for such uses, there would have been no motivation to achieve more efficient elimination of blood.

Thus, the improvements in the design of the infusion ports of the embodiment of the catheter of the subject invention described in Claims 2 and 5 offer significant improvements in treatment using that catheter, were not obvious, and contain allowable subject matter.

Applicants have amended Claim 1 to recite that the infusion ports are radially distributed about the circumference of the catheter shaft at the light treatment zone and longitudinally distributed along the length of the light treatment zone.

The embodiments of the subject invention previously disclosed in Claims 2 and 5 are now described in amended Claim 1 and are, therefore, withdrawn. Claims 3 and 4 are amended to reflect dependence on the currently amended Claim 1. Claims 6-9 and 11-26 are allowable as being dependent from allowable Claim 1. Claim 27 discloses an embodiment of the subject invention for inserting into a blood vessel that includes the novel and useful orientation of the infusion ports now described in currently amended Claim 1 and is, therefore, allowable.

Claims 16, 21-23 and 27 have been amended to change the reference from "balloon" to "occlusion balloon."

The Examiner rejected Claims 28-36 under 35 U.S.C. 102(b) as anticipated by Kittrell et al., U.S. Patent No. 5,104,392 (the “392 Patent”). The ‘392 Patent does not teach incorporating a fluorescent material into the distal end of the catheter shaft to provide a fluorescent emission when exposed to light from the light delivery optical fiber, but instead describes measuring tissue fluorescence, to monitor the amount of light reaching the tissue. To the contrary, the novel embodiment of the subject invention incorporates the innovative use of fluorescent material on the distal end of the catheter shaft, thereby permitting a quantitative measure of the amount of optical input power that reaches the light treatment zone. Thus, this novel embodiment of the subject invention would detect breakages in the light delivery fiber; thereby alleviating the risk of catastrophic treatment failure or undertreatment. See page 26, lines 8-10 of the application.

Applicants have amended Claim 28 to recite that a fluorescent material is incorporated into the distal end of the catheter shaft to provide a fluorescent emission when exposed to light from the light delivery optical fiber. In addition, applicants have incorporated into Claim 28 the novel and useful orientation of the infusion ports now described in currently amended Claim 1. Therefore, Claim 28 is allowable.

The embodiment of the subject invention previously disclosed in Claim 31 is now described in amended Claim 28 and is, therefore, withdrawn. Claims 29 and 30 are allowable as dependent on allowable Claim 28. Claim 32 is currently amended to reflect dependence on the currently amended Claim 1. Claim 34 describes an embodiment of the subject invention in which a fluorescent material is incorporated into the distal end of the catheter shaft to provide a fluorescent emission when exposed to light from the light

delivery optical fiber. In addition, it is currently amended to incorporate the novel and useful orientation of the infusion ports now described in currently amended Claim 1. Therefore, Claim 34 is allowable. Claim 35 is currently amended to correct an error referencing the claims from which it depends. Claim 36 is currently amended to correct an error referencing the claims from which it depends and to change the reference from "light detection optical element" to "wavelength selective optical element."

The Examiner rejects Claims 37-39 under 35 U.S.C. 102(b) as anticipated by the '653 Patent, although does not specifically address these claims in the Office Action.

The embodiments of the subject invention described in Claims 37-39, particularly useful for treating small vessels, are not anticipated by the '653 Patent. Claim 37 describes an embodiment of the subject invention in which the catheter shaft has a variable diameter that decreases at a transition point adjacent to the light treatment zone, wherein an infusion lumen in the catheter shaft also has a variable diameter that decreases at the transition point.

Claim 38 describes an embodiment of the subject invention in which the catheter shaft has a variable diameter that decreases at a transition point adjacent to the light treatment zone, wherein an infusion lumen terminates at the transition point.

The '653 Patent describes neither a catheter shaft nor an infusion lumen with a variable diameter. As disclosed on page 26, line 21 through page 28, line 12 of the application, using a catheter shaft with a variable diameter, containing an infusion lumen with a variable diameter, resolves the problem of inadequately flushing the vessel by allowing a higher pressure to be provided at the distal end of the catheter and improving the flushing of the vessel. In addition, this embodiment of the subject invention "allows

desired flow rather to be achieved while maintaining relatively low pressures, even when the diameter of the distal infusion lumen is small."

Certain benefits of the novel embodiment of the subject invention described in Claim 38 are described on page 28, line 13 through page 29, line 10 of the application. As discussed, this embodiment permits "high flush rates while maintaining a low cross section in the light treatment zone." See page 28, lines 13-14 of the application. In addition, terminating an infusion lumen at an infusion port at the transition point permits direction of the flush stream distally toward the light treatment zone. See page 29, lines 1-2 of the application.

Claim 39 is allowable as dependent from allowable Claim 38.

New Claims 40 and 41, dependent on allowable Claim 28, have been added. New Claims 42 and 43, dependent on allowable Claim 34, have been added. A new Claim 44, dependent on allowable Claim 37, and a new Claim 45, dependent on allowable Claim 38, have been added.